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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,309	04/20/2004	Michael B. Zemel	31894-199326	2567
26694	7590	07/13/2006	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20045-9998			LASTRA, DANIEL	
			ART UNIT	PAPER NUMBER
			3622	
DATE MAILED: 07/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/827,309

Applicant(s)

ZEMEL ET AL.

Examiner

DANIEL LASTRA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-24 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-24 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/06/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-3, 5-24 and 26-31 have been examined. Application 10/827,309 (METHODS OF PROMOTING CALCIUM CONSUMPTION FOR WEIGHT LOSS) has a filing date 04/20/2004 and is a division of 10066057 01/31/2002 is a division of 09654357 09/01/2000.

Response to Amendment

2. In response to Non Final Rejection filed 10/04/2005, the Applicant filed an Amendment on 03/06/2006, which amended claims 1, 22, 24, cancel claims 4, 25 and added new claims 28-31. Applicant's amendment overcame the Section 101 rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 6, 7, 8, 9, 10, 22, 23, 24, 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Said claims are not enabling because while the specification is enabling for those on low-calorie diet who are not already consuming calcium, said Specification does not provide enablement for on any diet and consuming any amount of dairy. Applicant's specification discloses the need to restrict

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calorie intake for the purpose of reducing weight and that the calcium supplements are given to individuals in conjunction with a dietary plan (see Applicant's specification paragraph 37). However, Applicant's claims do not recite anything about the need of reducing calorie intake, therefore, Applicant's claims are not enabling. Also, the article Got Milk? Getting Thinner? submitted by the Applicant on the IDS filed 03/06/2006, is cited as extrinsic evidence containing admission by one of the inventors, Michael Zemel, where he cited "that his research is often misunderstood because it's not a case of drink milk, lose weight. It works only for people who eat a low-calorie diet and who are not already consuming three servings of dairy". However, the Applicant never mentioned anything about calorie intake in the Applicant's claims and therefore, said claims are not enabling.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 31 recites "wherein the distributed information recommends at least about 102 portions of dairy per month". Nowhere, in Applicant's specification this limitation is disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 recites "wherein the distributed information recommends at least about 102 portions of dairy per month". The claim does not clearly teach what is the definition of a "portion".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5-20, 22-24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over The Milk Mustache Campaign (agcommcase.ifas.ufl.edu/mustache.html) in view of the article Randomised controlled trail of novel (Dialog file 149: 01811482).

As per claims 1, 22 and 24, The Milk Mustache Campaign (agcommcase.ifas.ufl.edu/mustache.html) teaches:

A method comprising communicating to a potential consumer that consuming a calcium-containing product may have a beneficial effect (see The Milk Mustache paragraph 4) the communicating being by an entity having a commercial interest in the consumption of the product (see paragraph 5 "Milk Processors of California"). The

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article The Milk Mustache fails to teach that said beneficial effect is on body weight or body fat. However, the article Randomised controlled trail of novel (Dialog file 149: 01811482) teaches that patients that put on a milk only diet had significant weight loss (see Randomised controlled trail of novel paragraphs 24 and 25). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that retailers of calcium-enriched products (such as dairy products), as taught by The Milk Mustache campaign would promote the consumption of said products by claiming that the consumption of said products would have a benefit against osteoporosis (see The Milk Mustache paragraph 1) and obesity (see Randomised controlled trail of novel paragraphs 24 and 25). Retailers of calcium-fortified products would be motivated to advertise the benefits of said products in combating diseases and/or maladies, such as osteoporosis and/or obesity, as said advertise benefits would bring more business to said retailers.

and wherein the communicating is by a method selected from the group consisting of verbal communication, pamphlet distribution, print media, audio tapes, magnetic media, digital media, audiovisual media, billboards, advertising, newspapers, magazines, direct mailings, radio, television, electronic mail, electronic media, banner ads, fiber optics, *and information on a product package, insert or label or directly accompanying the product* (see The Milk Mustache paragraph 5 "print advertising). The The Milk Mustache article does not teach electronic media, banner ads, and other methods of delivering promotions. However, Official Notice is taken that it is old and well known in the business art to advertise products using different communications method,

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such as verbal, e-mails, etc. It would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that manufacturers and retailers of calcium-fortified products would use all the available and affordable means to advertise to consumers the benefit of said products, so said consumers are aware of said benefits and purchase said products.

As per claim 2, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the communicating comprises providing information about suboptimal calcium consumption (see paragraph 1).

As per claim 3, The Milk Mustache Campaign teaches:

The method of claim 1, further comprising communicating an effect of calcium consumption on osteoporosis (see paragraph 1).

As per claim 5, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the effect on body weight comprises preventing or reducing obesity. However, the same argument made in claim 1 regarding this missing limitation is also made in claim 5.

As per claim 6, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the effect on body weight comprises preventing or reducing weight gain. However, the same argument made in claim 1 regarding this missing limitation is also made in claim 6.

As per claim 7, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the effect on body weight comprises weight loss. However, the same argument made in claim 1 regarding this missing limitation is also made in claim 7.

As per claim 8, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the effect on body weight comprises inducing a metabolic change in an individual. However, the same argument made in claim 1 regarding this missing limitation is also made in claim 8.

As per claim 9, The Milk Mustache Campaign teaches:

The method of claim 8, but fails to teach wherein the metabolic change comprises decreasing intracellular calcium concentrations ($[Ca^{2+}]_i$), stimulating lipolysis, inhibiting lipogenesis, increasing the expression of white adipose tissue uncoupling protein 2 (UCP2), reducing serum insulin levels, thermogenesis, or decreasing the levels of calcitrophic hormones. However, the same argument made in claim 1 regarding the linking of weight loss with drinking milk is made in claim 9. Also, one of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipose tissue.

As per claim 10, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the effect on body weight comprises preventing or reducing weight gain and/or adiposity in children. However, the same argument made in claim 1 regarding this missing limitation is also made in claim 10.

As per claim 11, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the communication pertains to a class of products to which the calcium-containing product belongs (see paragraph 1).

As per claim 12, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the product is a dairy product (see paragraph 1).

As per claim 13, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the product is a dietary supplement (see paragraph 1).

As per claim 14, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the product is a non-dairy foodstuff naturally high in calcium. However, Official Notice is taken that it is old and well known that certain vegetables such as broccoli are high in calcium and help to fight osteoporosis. It would have been obvious to a person of ordinary skill in the art that vegetable producers would also advertise the benefits of their products for the purpose of selling said products.

As per claim 15, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the product is a foodstuff fortified with calcium. However, the same rejection applied to claim 14 regarding this missing limitation is also applied to claim 15.

As per claim 16, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the product is selected from the group consisting of milk, yogurt and cheeses (see paragraph 1).

As per claim 17, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the product is a liquid supplemented with calcium. However, the same argument made in claim 14 regarding this missing limitation is also made in claim 17.

As per claim 18, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the entity is the manufacturer of the product (see paragraph 1).

As per claim 19, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the entity is a retailer of the product (see paragraph 5 "Milk processors in California").

As per claim 20, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the entity is a trade association whose members sell the product (see paragraph 5).

As per claim 23, The Milk Mustache Campaign teaches:

The method of claim 22 but fails to teach wherein the distributed information recommends at least about 57 portions of dairy per month. However, Official Notice is taken that it is old and well known in the business art that companies with financial interest in selling their products would recommend a minimum amount of consumption of said products for the purpose of selling more of said products. It would have been obvious to a person of ordinary skill in the art at the time the application was made, that companies of dairy products would advertise that said dairy products would need to be consumed a certain number of times to obtain a certain benefit so said companies would generate more income from said consumption.

As per claim 26, The Milk Mustache Campaign teaches:

The method according to claim 24 wherein said information pertains to a class of products to which said calcium-containing product belongs (see paragraph 1).

As per claim 27, The Milk Mustache Campaign teaches:

The method according to claim 24, wherein said class of products is dairy products (see paragraph 1).

As per claim 26, The Milk Mustache Campaign teaches:

The method according to claim 24, wherein said information pertains to a class of products to which said calcium-containing product belongs (see paragraph 1).

As per claim 27, The Milk Mustache Campaign teaches:

The method according to claim 24, wherein said class of products is dairy product (see paragraph 1).

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over The Milk Mustache Campaign (<http://agcommcase.ifas.ufl.edu/mustache.html>) in view of the article Randomised controlled trial of novel (Dialog file 149: 01811482) in view of Christiansen (US 6,159,530).

7. As per claim 21, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the product is identified by a trademark. However, Christiansen teaches a trademark calcium-fortified product (see Christiansen column 9, lines 20-35; "Calcium taste free"). Therefore, the same argument made in claim 1 is made in claim 21.

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9. Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over The Milk Mustache Campaign (<http://agcommcase.ifas.ufl.edu/mustache.html>) in view of the article Randomised controlled trail of novel (Dialog file 149: 01811482) in view of the article Jones sports mustache for milk (Dialog file 397: 00150522).

As per claim 28, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the communication recommends consuming calcium daily in an amount of at least about 773 mg. However, the article Jones sports mustache for milk (Dialog file 397: 00150522) teaches recommending about 1 gram of calcium a day (i.e. three glasses of milk a day). Therefore, it would have been obvious to a person of ordinary skill that about a 1gram a day would read into at least 773mg a day. It would have been obvious to a person of ordinary skill in the art at the time the application was made, that companies of dairy products would advertise that said dairy products would need to be consumed a certain number of times to obtain a certain benefit so said companies would generate more income from said consumption.

As per claim 29, The Milk Mustache Campaign teaches:

The method of claim 1, but fails to teach wherein the communication recommends consuming calcium daily in an amount of at least about 1000 mg. However, the article Jones sports mustache for milk (Dialog file 397: 00150522) teaches recommending about 1 gram of calcium a day (i.e. three glasses of milk a day). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, that companies of dairy products would advertise that said

dairy products would need to be consumed a certain number of times to obtain a certain benefit so said companies would generate more income from said consumption.

As per claim 30, The Milk Mustache Campaign teaches:

The method of claim 1, wherein the communication recommends consuming calcium daily in an amount of at least about 1,346 mg. However, the same argument made in claim 28 regarding this missing limitation is also made in claim 30.

As per claim 31, The Milk Mustache Campaign teaches:

The method of claim 22 wherein the distributed information recommends at least about 102 portions of dairy per month. However, the same argument made in claim 28 regarding this missing limitation is also made in claim 31.

Response to Arguments

10. Applicant's arguments with respect to claims 1-3, 5-24 and 26-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- The article US government questions effectiveness of milk advertising (Dialog file 112: 01171968) teaches that the amerca's milk mustache advertising campaign has produced no evidence that it's increased consumption.
- The Article Crash diets do work single-food regimes knock off the pounds faster than conventional calorie cutting (Dialog file 781: 04337869) teaches that overweight volunteers who lived on milk for 16 weeks lost an average of a stone and half each.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL LASTRA whose telephone number is 571-272-6720 and fax 571-273-6720. The examiner can normally be reached on 9:30-6:00.

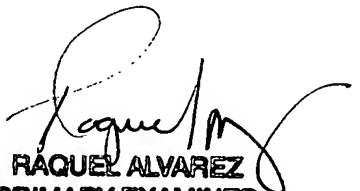
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ERIC W. STAMBER can be reached on 571-272-6724. The official Fax number is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel Lastra
May 16, 2006



RAQUEL ALVAREZ
PRIMARY EXAMINER